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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/735,601	12/12/2003	Jonathan F. Smith	95-02	2496

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EXAMINER	
KELLY, ROBERT M	
ART UNIT	**PAPER NUMBER**
1633	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/735,601	SMITH ET AL.	
	Examiner	Art Unit	
	Robert M. Kelly	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 November 2006*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-31* is/are pending in the application.

4a) Of the above claim(s) *1-15 and 20-31* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *15-19* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *12 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *8/26/05; 10/12/04; 10/7/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicant's amendment and response to restriction requirement of 9/8/06 are entered.

Claims 27-31 are newly added.

Claim 20 is amended.

Claims 1-31 are pending.

Election/Restrictions

Applicant's election with traverse of Group II, Claims 16-19 in the reply filed on 11/30/07 is acknowledged. The traversal is on the ground(s) that the intended use of the alphaviral particles is for the methods, and the preparation of the particles is delineated in Group II. This is not found persuasive because the particle preparation could be made by other methods, and claimed methods of use are not the only use for such particles, as several rejections make clear within this action. Moreover, the search of relevant art for a product will not identify all the relevant art for the use of the product, in particular such art rejections do not take into account the various aspects under 35 USC 112 which need to be taken into account with respect to novel claimed methods (e.g., enablement and written description), which would require further search and examination consideration.

It is further noted that the species requirement is withdrawn in light of the Examiner finding art on each species encompassed.

The requirement is still deemed proper and is therefore made FINAL.

Oath/Declaration

Applicant's oath and declaration of 4/2/04 is accepted.

Priority

Applicant's priority is accepted and meets the criteria required.

Information Disclosure Statement

The listing of references in the specification on pages 48-49 is not a proper information disclosure statement. 37 CFR 1.98(b) requires a list of all patents, publications, or other information submitted for consideration by the Office, and MPEP § 609.04(a) states, "the list may not be incorporated into the specification but must be submitted in a separate paper." Therefore, unless the references have been cited by the examiner on form PTO-892, they have not been considered.

Applicant's IDSs of 8/26/05, 10/12/04, and 10/7/04 have been considered, initialed, and signed. However, it is noted that Applicant has failed to place the author name into several citations in the IDS of 8/26/05. Such improper citation has nonetheless been considered, however, Applicant is reminded to fill out the forms properly, the top of the form used contained the information as to what was required, including the author's name. Please refer to such in the future, prior to submitting an IDS.

Drawings

Applicant's drawing is accepted.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 17-19 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 17-19 are vague and indefinite in that the metes and bounds of the term "derived from", in each instance, are unclear. It is unclear as to the nature and number of steps required to obtain a "derivative" of an antigen of any particular organism. The term implies a number of different steps that may or may not result in a change in the functional characteristics of the antigen as present from the source that it is "derived from".

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 16 and 18-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 6 of U.S. Patent No. 7,090,852. Although the conflicting claims are not identical, they are not patentably distinct from each other because the instant specification covers similar VEE replicons for inducing immunity to viruses, and Claim 6 of the patent claims a composition of such replicons encoding up to several specific MBGV proteins, which is useful for inducing immune responses to the Marburg virus. Further, the instant specification teaches that the replicons may be used to induce immunity to any virus. Hence, the compositions claims are obvious over the patent, the Artisan would have been motivated to make them in order to produce immunity to the Marburg virus. Moreover, the Artisan would have had a reasonable expectation of success, as the claim teaches that the compositions may be used as a vaccine.

Claims 16 and 18-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-3 and 8-9 of U.S. Patent No. 6,783,939. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the claims are that the patent claims are drawn to specific viral proteins as antigens of HIV. However, the instant specification teaches any particular combination of such antigens (e.g., pp. 4-5, paragraph bridging). Hence, in view of the patent, it would have been obvious to make the instantly claimed invention. The Artisan would have been motivated to do so in order to produce the proteins in immune responses. Moreover, the artisan would have had a reasonable expectation of success, as the patent taught that such particle compositions could be so-used.

Claims 16 and 18-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1, 3-8, 10-15, 33-40, 44-49 and 51-77 of U.S. Patent No. 6,521,235. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the inventions are the patent claiming specific viral replicons, claiming specific attenuating mutations, and specific viral antigens. Moreover, the claims of the patent, except claims 3-4, do not claim specific antigens to protozoa or bacteria or the genera of any viral antigens. However, the instant specification teaches attenuating mutations to the E1-E3 (e.g., p.6), and the specific attenuating mutations (the references cited in e.g., p. 6). Further, the patent teaches protozoa, bacterial, and viral antigens in general (e.g., cols. 5-6). Still further, the instant specification teaches the specifically claimed viruses for their antigens (e.g., p. 12). Hence, in light of US Patent No 6,521,235, it would have been obvious to make the instant invention. The Artisan would have been motivated to do so in order elicit immune responses, as taught in the patent. Moreover, the Artisan would have expected success, as the patent teaches such.

Claims 16, 18-19 rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 32, 34-35, 37, 40, 42, 44-45, 47, 50-52, 54-55, 57, 60, 62, 64-65, 67, 70, 72, 74-75, 77, 80, 82, 84-90 of U.S. Patent No. 6,531,135. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the claims are the patent claiming specific alphavirus replicons. Further, the specifications each direct the artisan to use encoding sequences from similar viruses (e.g.,

PATENT, col. 5). Hence, from the disclosure of the patent, it would have been obvious to make the instantly claimed invention. The Artisan would have been motivated to do so in order to provide immune responses, as taught in the patent. Moreover, the Artisan would have had a reasonable expectation of success, as the patent teaches it can be done.

Claims 16 and 18-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-13, 16-17, 19, 23-35, 37-55, 57, and 61 of U.S. Patent No. 6,156,558. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the instant claims and the patent claims are that the patent encompasses not only claims the generic alphavirus, but also claims specific viruses encompassed, and further comprises specific attenuating mutations. However the instant specification teaches attenuating mutations in general, and teaches the various specific viruses claimed. Moreover, the patent, while not specifically claiming antigens, does teach the use of viral antigens (e.g., col. 5). Hence, in light of the disclosure of the patent, the instantly rejected claims are obvious. The Artisan would have been motivated to make the compositions, as the patent teaches that such may induce immune responses. Moreover, the Artisan would have expected success, as the patent teaches such.

Claims 16 and 18-19 are rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 22-26, 28-29, 31-34, and 36-37 of U.S. Patent No. 6,541,010. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences between the instant claims and the patent's claims are

that the patent has attenuating mutations encompassed, specific viruses encompassed, and no specific heterologous sequence claimed. However, the patent's specification teaches prokaryotic, eukaryotic, protozoa, and viral antigens (e.g., cols. 11-12, paragraph bridging). Moreover, the instant specification teaches to attenuate the same genes, and use of similar viral replicons. Hence, in view of U.S. Patent No. 6,541,010, the artisan would have been motivated to make the claimed invention. The Artisan would have also expected success, as the patent teaches that such can be done.

Claims 16-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-21 of copending Application No. 10/517,083. Although the conflicting claims are not identical, they are not patentably distinct from each other because the differences are that the patent's claims are drawn to VEE alphaviral replicons, and specific mutations to attenuate such particles. However, the instant specification teaches VEE replicons (e.g. , p. 12) and further teaches attenuating mutations in VEE are desirable (e.g., p. 20). Lastly, it should be noted that in 10/517,083, Applicant has specifically defined the article "a" or "an" to encompass multiples, and hence, all these claims are drawn to multiple antigens. Lastly, the 10/517,083 Application teaches all the same species from which the antigens are derived (e.g., pp. 27-29). Hence, the instantly rejected claims are obvious over that of the claims and specification of the other Application. The Artisan would have been motivated to make them, in order to produce immune responses. Moreover, the Artisan would have had a reasonable expectation of success, as the other Application teaches such use.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 16 and 18-19 provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 2-9, 17-18, and 23-26 of copending Application No. 10/929,234. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the instant claims are drawn to a minimum of a generic pair of antigens from a virus, both specifications teach HIV, and the same antigens, and HIV-1, as well as the instant specification teaching each specific type of alphaviral replicon particle claimed, and teaching attenuating mutations to the same genes. Hence, in light of the teachings and claims of 10/929,234, the Artisan would have been motivated to make the presently claimed invention, as it is taught for inducing immune responses. Further the Artisan would have expected success, as the 10/929,234 Application teaches that it would work.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claims 16-19 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 18, 24, and 25 of copending Application No. 11/132,711. Although the conflicting claims are not identical, they are not patentably distinct from each other because while the other Application's claims are drawn to TC-83 viral replicons, and do not teach claim any particular heterologous sequences, the present specification teaches the use of TC-83 strain, because of its naturally attenuated phenotype (e.g., p. 17), and the other

Application teaches all the same specifically claimed species of antigen (e.g., p. 25). Hence, in light of the teachings and claims of the 11/132,711 Application, it would have been obvious to make the present invention. The Artisan would have been motivated to do so in order to treat various disorders. Moreover, the Artisan would have expected success, as the other Application teaches it will work.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

It is noted that the instant Application and the various other patents and Applications with at least one common inventor are subject to restriction requirements between the compositions, methods of making, and methods of using, precluding certain rejections under double patenting. However, future changes in such restriction requirements (i.e., rejoinder in the instant Application, or in another Application) may subject these claims to rejections not held above.

It is further noted that the various inventors have been quite prolific in the field of alphaviral replicons, attaining approximately 24 patents to date, and having another 13 Applications in various stages of prosecution. Applicant should beware that, depending on how these Applications, as well as the present Application is amended, new rejections may be imposed under double-patenting.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.
>
> (e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.
>
> (f) he did not himself invent the subject matter sought to be patented.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by US PAT NO 6,521,235 to Johnston, et al., patented February 18, 2003; and

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(f) because the applicant did not invent the claimed subject matter.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

With regard to the claims rejected in this section, Johnston teaches the alphaviral particle replicon compositions, as claimed, wherein the alphaviral replicons comprise coding regions for more than one antigen (e.g., Claims 16 and 18-19), and further, Johnston teaches that the antigens can come from various viruses, protozoa, and bacteria (e.g., col. 6; claims).

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 7,090,852 to Hevey, et al.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Hevey teaches alphaviral amplicon particle compositions, comprising multiple antigens of Marburg virus (e.g., ABSTRACT; cols. 4-6, col. 7, paragraph 5; and Claim 6).

Hence, Hevey anticipates the claims.

Claims 16 and 18-19 rejected under 35 U.S.C. 102(e) as being anticipated by US Patent No. 6,783,939 to Olmstead, Patented 8/31/04.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

As shown by claims 2-3 and 8-9, the Olmstead teaches compositions of alphaviral replicon particles, comprising one or more encoded antigens from gag, env, and pol. Hence, Olmstead anticipates the instant claims.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,521,235 to Johnston, et al., Patented 2/18/03.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Johnston teaches alphaviral replicon vectors (ABSTRACT), encoding more than one antigen (e.g., Claims 3-4), which may be of viral, protozoan, or bacterial origin (e.g., cols. 5-6).

Hence, Johnston anticipates the claims.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,531,135 to Johnston, et al., Patented 3/11/03.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the

inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Johnston teaches alphaviral replicon particles (e.g., ABSTRACT), encoding more than one antigen (e.g., Claims 34-35), which may be from several viral sources (e.g., col. 5).

Hence, Johnston anticipates the claims.

The following pair of rejections is made with, alternatively, the PGPub and patent, of the same application, however for sake of compactness, the analysis is only directed to the patent, as the Application has the same disclosure.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent Publication No. 20020034521 to Lee, et al., Published 3/21/02 and

Claims 16 and 18-19 are also rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,495,143, to Lee, et al., Patented 12/17/02.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lee teaches VEE replicon particles (e.g., col. 4), and compositions of such wherein the replicon particles encode a plurality of botulinum bacteria antigens (e.g., Claim 28).

Hence, Lee anticipates the claims.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,632,640 to Lee, et al., Patented 10/14/03.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lee teaches VEE replicon particle compositions encoding 2 distinct antigens of Staphylococcus aureus endotoxins (e.g., col. 3, paragraphs 2-3).

Hence, Lee anticipates the cited claims.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,770,479 to Lee, et al., patented August 3, 2004.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Lee teaches a composition of VEE replicons (e.g., EXAMPLE 2), encoding more than one antigen of anthrax (e.g., Claim 15).

Hence, Lee anticipates the cited claims.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent Publication No. 2002/0164582 to Hart, et al., Published 11/7/02.

Hart teaches VEE replicon particles (e.g., paragraph 0025), encoding several Ebola virus antigens (e.g., paragraphs 0025 and Claim 59). (It is noted that the composition claim states that the DNA encodes these proteins, but the specification teaches that the DNA may be used to make the replicon particles, and hence, this evidences that the particles would contain the same sequences.)

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,517,842 to Hevey, et al., Patented 2/11/03

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Hevey teaches VEE replicon particles (e.g., col. 2, paragraph 6), encoding one or more Marburg virus antigens (e.g., col. 3, paragraph 4).

Hence, Hevey anticipates the cited claims.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00.

Johnston teaches a plurality of alphaviral particles encoding a plurality of antigens (e.g., Claim 37). Moreover, Johnston teaches such antigens being from viral sources (e.g., col. 5).

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(a) as being anticipated by U.S. Patent No. 6,451,592 to Dubensky, et al., Patented 9/17/02; and

Claims 16 and 18-19 are also rejected under 35 U.S.C. 102(e) as being anticipated by U.S. Patent No. 6,451,592 to Dubensky, et al., Patented 9/17/02.

The applied reference has a common inventor with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Dubensky teaches a composition of alphaviral replicons comprising multiple heterologous sequences (e.g., col. 3, paragraph 4). Moreover, such encoding heterologous sequences can be antigens to viruses (e.g., cols. 33-34, paragraph bridging).

Hence, Dubensky anticipates the claims.

Claims 16 and 18-19 are rejected under 35 U.S.C. 102(b) as being anticipated by U.S. Patent No. 5,792,462 to Johnston, et al., Patented 8/11/98.

Johnston teaches a composition of VEE replicons encoding more than one Lassa fever virus protein, which are in a composition, administered to BHK cells (e.g., EXAMPLE 4).

Hence, Johnston anticipates the claims.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 16-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00, Nestle, et al. (1998) Nature Medicine, 4(3): 328-32, and Smooker, et al. (2000) Vaccine, 18: 2533-40.

It is noted that the Nestle reference is only supplied as the abstract, as the Examiner was unable to obtain the full reference prior to the date that this Action is submitted. However, such abstract is sufficient to describe the aspects required of the reference.

Johnston teaches the use of similar alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3). However, Johnston does not teach a plurality of replicons encoding a plurality of antigens, or the use of antigens to cancer.

On the other hand, Nestle teaches a cocktail of peptides used to produce cancer immunity (e.g., ABSTRACT), and Smooker demonstrates that a library of genes may be administered to develop an immune response.

Hence, at the time of invention, it would have been obvious to make a plurality of alphaviral replicons encoding the different peptides of Nestle. The Artisan would have been motivated to do so to produce an immune response to cancer, using the method of Smooker instead of actual delivery of the polypeptides. Moreover, the Artisan would have had a reasonable expectation of success, as Smooker had demonstrated that a plurality of antigens could have been so-delivered and Nestle teaches that the plurality of peptides produced immune response to cancer.

Claim 16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00, and Smooker, et al. (2000) Vaccine, 18: 2533-40.

Johnston teaches the use of similar alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3). However, Johnston does not teach a plurality of replicons encoding a plurality of antigens, or the use of antigens to protozoans.

On the other hand, Smooker teaches a library of epitopes, expressed on separate plasmids (a library), for immunizing mice against Plasmodium chabaudi, a protozoan (ABSTRACT).

Hence, at the time of invention, it would have been obvious to make a library of alphaviral replicon particles encoding different foreign antigens of the protozoan. The Artisan would have been motivated to do so to immunize mice, thereby providing increased protection from Plasmodium chabaudi. The Artisan would have also have a reasonable expectation of success, as not only had Johnston demonstrated that immune responses could also be elicited, but Smooker had demonstrated the library of encoded proteins could induce immune protection from such protozoan.

Claims 16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,235,290 to Brunham, Patented 5/22/01 and U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00 and Smooker, et al. (2000) Vaccine, 18: 2533-40.

Brunham teaches a DNA vaccine against Chlaymidia (e.g., ABSTRACT) and further teaches to design a multivalent vaccine using various forms of the MOMP gene, in order to provide increased immunity to more strains of Chlaymidia (e.g., col. 5, paragraph 5).

Johnston teaches the use of similar alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3).

Smooker teaches a library of epitopes, expressed on separate plasmids (a library), for immunizing mice against Plasmodium chabaudi, a protozoan (ABSTRACT).

Hence, at the time of invention, it would have been obvious to modify the composition of Brunham to contain different antigens of MOMP from different strains of chlaymidia in the

vectors of Johnston. The Artisan would have been motivated to do so to increase the number of chlaymidia strains to which an immune response is elicited. Moreover, the Artisan would have had reasonable expectation of success, as Smooker had taught that large libraries of particles could elicit immunity when administered as DNA vaccine.

Claims 16-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 5,866,553 to Donnelly, et al., Patented 2/2/99, U.S. Patent No. 6,156,558 to Johnston, et al., Patented 12/5/00 and Smooker, et al. (2000) Vaccine, 18: 2533-40.

Donnelly teaches eliciting immune responses to papilloma virus via DNA constructs encoding papilloma virus gene products (e.g., ABSTRACT, TITLE). Further, several antigens are taught for such encoded genes, which may be used in combination (e.g. col. 5, paragraph 2). Still further, it is noted that papilloma virus is not only a virus, but a major cause of cancer in women (cervical cancer), and hence, such immunization is also against cancer.

Johnston teaches the use of the equivalent alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3).

Smooker teaches a library of epitopes, expressed on separate plasmids (a library), for immunizing mice against Plasmodium chabaudi, a protozoan (ABSTRACT).

Hence, at the time of invention, it would have been obvious to modify the composition of Donnelly to contain different antigens of HPV in the alphaviruses of Johnston. The Artisan would have been motivated to do so to provide immunity against the virus HPV and cancer.

Moreover, the Artisan would have had reasonable expectation of success, as Smooker had taught that large libraries of particles could elicit immunity.

Claims 16 and 18-19 are rejected under 35 U.S.C. 103(a) as being unpatentable over U.S. Patent No. 6,309,642 to Cutler, et al., Patented 10/30/01, U.S. Patent No. 6,156,558 to.Johnston, et al., Patented 12/5/00 and Smooker, et al. (2000) Vaccine, 18: 2533-40.

Cutler teaches several antigens designed to elicit immunity to Candida (a yeast and fungus), which may be delivered a polynucleotides encoding the antigens (e.g., ABSTRACT, CLAIMS).

Johnston teaches the use of the equivalent alpha-viral replicon particles, in vaccines. (E.g., ABSTRACT; col. 3, paragraph 4; col. 4, paragraph 2; cols. 7-8, paragraph bridging.) Moreover, Johnston demonstrates that the particles are sufficient to produce immune responses against foreign gene encoded proteins (e.g., FIGURE 3).

Smooker teaches a library of epitopes, expressed on separate plasmids (a library), for eliciting immunity to organisms (ABSTRACT).

At the time of invention, it would have been obvious to modify the methods of Cutler, by making several alphaviral replicon particles as taught by Johnston to encode different antigens as taught by Cutler. The Artisan would have been motivated to do so to provide immunity to Candida, as Johnston taught that such DNA immunization would provide similar immunity. Moreover, the Artisan would have had a reasonable expectation of success, as Smooker taught that multiple antigens could be delivered to produce immune responses.

Conclusion

No Claim is allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Robert M. Kelly, Art Unit 1633, whose telephone number is (571) 272-0729. The examiner can normally be reached on M-F, 9:00am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Joseph Woitach can be reached on (571) 272-0739. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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